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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: U.S. Patent No. 5,061,703
Inventors: Joachim BORMANN, Markus GOLD, and Wolfgang SCHATTON
Assignee: Merz Pharma GmbH & Co. KGaA
Title: ADAMANTANE DERIVATIVES IN THE PREVENTION AND TREATMENT OF
CEREBRAL ISCHEMIA
Issue Date: October 29, 1991

SUPPLEMENT TO REQUEST FOR EXTENSION OF PATENT TERM
UNDER 35 U.S.C. § 156

Mail Stop Patent Ext.
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This supplement relates to the pending request for extension of the term of U.S. Patent No. 5,061,703 ("the '703 patent") pursuant to 35 U.S.C. § 156, which was submitted on December 9, 2003 by Forest Laboratories, Inc. ("Forest") acting as agent of the patent owner Merz Pharma GmbH & Co. KGaA ("Merz"), and is submitted to indicate that the '703 patent was reexamined by the U.S. Patent and Trademark Office, and a Certificate of Reexamination was issued on November 7, 2006. A copy of the Certificate of Reexamination is attached as Exhibit A.

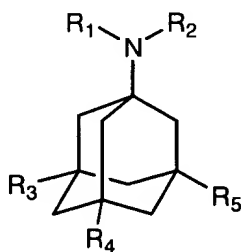
As a result of the reexamination proceeding, claims 1 and 10 were amended, the patentability of claims 2-9 and 11-13 was confirmed, and claims 14-19 were added.

All information previously provided in the December 9, 2003 Request for Extension of Patent Term Under 35 U.S.C. § 156 remains accurate. In particular, the '703 patent continues to claim a method of using NAMENDA™ (memantine hydrochloride), which is approved for the treatment of moderate to severe dementia of the Alzheimer's type, because claim 10 remains explicitly directed to the treatment of Alzheimer's disease and refers to independent claim 1 for the generic formula that continues to encompass memantine hydrochloride, as explained in the December 9, 2003 Request.

Claims 10 and 1 are reproduced below, illustrating the amendments that were made as a result of the reexamination proceeding:

10. A method according to claim 1 for the treatment of Alzheimer's disease, wherein said adamantane derivative is memantine and said effective amount is from about 0.01 to 100 mg/kg.

1. A method for the prevention or treatment of cerebral ischemia comprising the step of orally administering, to a patient diagnosed with Alzheimer's disease and in need thereof, an effective amount of an adamantane derivative of the general formula



wherein

R₁ and R₂ are identical or different and represent hydrogen or a straight or branched alkyl group of 1 to 6 C atoms or, in conjunction with N, a heterocyclic group with 5 or 6 ring C atoms;

wherein

R₃ and R₄ are identical or different, being selected from hydrogen, a straight or branched alkyl group of 1 to 6 C atoms, a cycloalkyl group with 5 or 6 C atoms, and phenyl;

wherein

R₅ is hydrogen or a straight or branched C₁-C₆ alkyl group; and
wherein

R₁, R₂, R₃, R₄, and R₅ do not all represent hydrogen simultaneously;
or a pharmaceutically-acceptable salt thereof.

The adamantane derivative of the general formula shown in claim 1 represents memantine hydrochloride when: R¹ and R² are hydrogen; one of R³, R⁴, and R⁵ is hydrogen and the remaining two of R³, R⁴, and R⁵ are methyl; and the pharmaceutically acceptable salt is the hydrochloride salt. See '703 patent at col. 4, lines 32-37. Additional claims that cover a method for using the approved product include claims 2, 3, 6, 8, and 11-13.

Forest, acting as agent for the patent owner Merz, requests that the Commissioner grant an extension of 1250 days to U.S. Patent No. 5,061,703.

Favorable action is earnestly solicited.

Dated: December 27, 2006

Respectfully submitted,

By 

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Patent No.. (if known): 5,061,703

Attorney Docket No.: 03269/8200177-000

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on December 27, 2006
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Signature

Lillian Garcia

Typed or printed name of person signing Certificate

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Supplement To Request For Extension Of Patent Term Under 35 U.S.C. §
156 (3 pp.)
Exhibit A (3 pp.)
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